UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NOVARTIS VACCINES AND DIAGNOSTICS, INC., NOVARTIS PHARMA AG, and GRIFOLS WORLDWIDE OPERATIONS LIMITED,	:	18cv2434(DLC)
Plaintiffs,	:	OPINION AND ORDER
-v-	:	
REGENERON PHARMACEUTICALS, INC.,	:	
Defendant.	:	

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DENISE COTE, District Judge:

Novartis Vaccines and Diagnostics, Inc., Novartis Pharma AG, and Grifols Worldwide Operations Limited (collectively, "Novartis") commenced this action on March 19, 2018 against Regeneron Pharmaceuticals, Inc. ("Regeneron") alleging patent infringement. This Opinion resolves a discovery dispute between the parties that is of importance to Novartis's demand for its lost profits as damages for Regeneron's infringement. For the reasons explained below, Novartis may not rely on a spreadsheet it produced after the close of discovery that identifies for the first time its net sales and profits.

Background

Since 2007, Novartis has manufactured and sold a drug called Lucentis that treats wet age-related macular degeneration and other eye disorders. A non-party company manufactures the active ingredient in Lucentis in the United States and then ships the ingredient to plaintiff Novartis Pharma AG ("Pharma") in Switzerland. Pharma then finishes the manufacturing of Lucentis and sells it to non-party affiliate distributors for sale throughout the world. Pharma has entered into

supplier/distributor agreements with these non-party affiliate distributors (the "Agreements"). The Agreements address the pricing, sale, and distribution of all of Pharma's products, including Lucentis, that are distributed by the affiliate, but do not mention Lucentis by name.

In 2011, Novartis brought an action in Delaware against three other biotechnology companies, seeking damages for infringement of the same patent at issue here. See Complaint, Novartis Vaccines & Diagnostics, Inc. et al. v. MedImmune LLC et al., No. 11cv00084, 2011 WL 445672 (D.Del. Jan. 26, 2011). That litigation settled in 2014 before discovery began on Novartis's damages theories.

In 2011, Regeneron began manufacturing and selling a product called Eylea that is a competitor of Lucentis. Novartis alleges that Eylea's active ingredient is manufactured in the United States through a process that uses a cell line that infringes Novartis's patent at issue in this suit.

On March 19, 2018, Novartis filed this action against Regeneron for patent infringement. Novartis seeks damages for Regeneron's alleged patent infringement under both reasonable-royalty and lost-profits theories. As Novartis made explicit recently, it seeks lost-profits damages only on behalf of Pharma, not on behalf of Pharma's affiliated distributors.

To the extent the patent infringement claims are identical to those litigated in the Delaware action, Novartis has been permitted to rely here on the discovery it produced in that earlier litigation. Because there was no damages discovery in the Delaware action, however, discovery regarding damages has been undertaken here for the first time.

On June 26, 2018, Regeneron served its first set of document requests, seeking all documents on which "Novartis intends to rely upon in this litigation to support its claims or defenses." On June 29, Novartis served its initial disclosures, pursuant to Rule 26(a)(1), Fed. R. Civ. P. In these initial disclosures, Novartis identified "Financial documents relating to sales and profits generated by Lucentis® outside the United States." These initial disclosures also contained a section titled "Information Related to Calculation of Damages" in which Novartis disclosed that it was seeking compensatory damages, including lost profits, and stated that "Novartis will make available for inspection and copying, at the appropriate time, documents and/or computations, together with supporting documents, concerning any claim for compensatory damages."

On December 11, 2018, Regeneron served its first set of interrogatories on Novartis. Interrogatory number eight sought "all agreements or licenses that concern . . . Lucentis."

On January 24, 2019, Regeneron served a third set of document requests. Request number 42 sought

> Documents sufficient to show the revenues or profits generated for each Plaintiff by Lucentis® . . . including monthly, quarterly, or annual amounts of revenue from sales; the allocation of profits and booking of profits for each sale of Lucentis®; monthly, quarterly, or annual number of prescriptions; monthly quarterly, or annual gross profits from sales; monthly quarterly, or annual net profits from sales; together with all expenses, deductions, allowances, or other adjustments used to calculate net profits; or monthly, quarterly, or annual amounts spent on marketing, advertising, promoting, selling, and providing samples, both in the aggregate and based on the particular type of expense.

Fact discovery closed on March 29. During and after the fact discovery period, both parties, but primarily Regeneron, brought a significant number of discovery disputes to the Court's attention. Several of Regeneron's requests for court intervention were triggered by its contention that Novartis had not yet produced all relevant Agreements concerning Lucentis.

At a February 8 telephone conference, the parties were ordered to agree to a firm deadline for production of all agreements or licenses concerning Lucentis with the warning that any delay at this stage in the litigation in producing documents that support the plaintiffs' damages claim could affect the plaintiffs' ability to recover damages. On several occasions, Novartis assured Regeneron and the Court that it had been actively engaged in the discovery process and had produced all

agreements and/or licenses related to its patent and Lucentis. This included representations in letters to the Court dated February 20 and March 15 and in communications with Regeneron on March 12 and March 27.

Another discovery dispute, born out of Novartis's complaint that Regeneron had failed to provide adequate damages-related discovery about its supply chain for Eylea, gave rise to a telephone conference on March 22. Following this conference, the Court ordered briefing on Novartis's theory of damages. Novartis filed its opening brief on this issue on March 29, Regeneron filed a responsive brief on April 5, and Novartis filed a reply brief on April 16. In its April 5 brief, Regeneron argued, inter alia, that Novartis could not claim lost-profits damages for non-party affiliates' sales of Lucentis. That same day -- which was also the deadline for the parties to exchange opening expert reports -- Novartis produced the spreadsheet calculating Pharma's lost profits discussed below (the "Pharma Spreadsheet"). Novartis also produced on April 5 three royalty report spreadsheets showing country-by-country royalties for three quarters of 2015.

On April 12, Novartis produced thirty-six Agreements; on April 16, it produced another eight. In a letter of April 16, Regeneron moved to preclude Novartis from using the Pharma Spreadsheet and forty-four Agreements.

The Pharma Spreadsheet, titled "NPhAG Lucentis Overview in kUSD at Period Rates," consists of three rows -- net sales of Lucentis, function costs, and volume units sold of Lucentis -- and columns for each quarter and year-end between 2011 and 2015. According to Novartis, the Spreadsheet reflects sales data for Lucentis only in those countries in which Eylea is also sold. On the basis of the data presented in the Pharma Spreadsheet, Novartis claims almost $537 million in lost profits for Pharma. Prior to April 5, Novartis had produced a spreadsheet titled "Global Net Sales and Costs for Lucentis Group," which showed net sales and function costs associated with Lucentis for Pharma and its non-party affiliates for each quarter from 2011 through the first quarter of 2015 without any separate presentation of these numbers for Pharma alone.

A hearing was held on April 24 to address, inter alia, Regeneron's request to preclude use of the late-produced Agreements and the Pharma Spreadsheet. At the conclusion of the hearing, this Court issued a preliminary ruling precluding use of "any supply/distribution agreements between [Pharma] and its non-party affiliates" and "any spreadsheets first produced to Regeneron on April 5, or thereafter."[1] In response to Novartis's

[1] Regeneron asserts that the Court's April 24 ruling precluding the use of any spreadsheets first produced to Regeneron on April 5 or thereafter encompasses three royalty reports from 2015 produced on April 5. These reports were not the subject of

request to brief this issue, the Court invited Novartis to submit briefing in the form of a motion for reconsideration and ordered that briefing on the issue address whether the ruling precluding the use of these late-produced documents has "the practical effect of excluding any claim by plaintiffs for lost-profits damages." Briefing was fully submitted on May 24.

Discussion

The standard for granting a motion for reconsideration is "strict." Analytical Surveys, Inc. v. Tonga Partners, L.P., 684 F.3d 36, 52 (2d Cir. 2012) (citation omitted). "[R]econsideration will generally be denied unless the moving party can point to controlling decisions or data that the court overlooked." Id. (citation omitted). "A motion for reconsideration should be granted only when the defendant identifies an intervening change of controlling law, the availability of new evidence, or the need to correct a clear error or prevent manifest injustice." Kolel Beth Yechiel Mechil of Tartikov, Inc. v. YLL Irrevocable Tr., 729 F.3d 99, 104 (2d Cir. 2013) (citation omitted). It is "not a vehicle for relitigating old issues, presenting the case under new theories,

Regeneron's April 16 motion nor were they discussed at the April 24 hearing. They are not therefore subject to the Court's April 24 ruling.

securing a rehearing on the merits, or otherwise taking a second bite at the apple." Analytical Surveys, 684 F.3d at 52 (citation omitted). The decision to grant or deny the motion for reconsideration is within "the sound discretion of the district court. . . ." Aczel v. Labonia, 584 F.3d 52, 61 (2d Cir. 2009) (citation omitted).

Patent Act Damages

In this case, Novartis seeks either a reasonable royalty award or lost-profits damages, whichever is greater. Under the Patent Act, "the court shall award [the patent owner] damages adequate to compensate for the infringement but in no event less than a reasonable royalty for the use made of the invention by the infringer." 35 U.S.C. § 284. To recover compensatory or lost-profits damages "the patentee must establish . . . [the] answer to a simply stated question: Had the Infringer not infringed, what would the Patent Holder-Licensee have made?" Mentor Graphics Corp. v. EVE-USA, Inc., 851 F.3d 1275, 1284 (Fed. Cir. 2017), cert. dismissed, 139 S. Ct. 44 (2018) (citation omitted). "To recover lost profits, a patent owner must prove a causal relation between the infringement and its loss of profits." Georgetown Rail Equip. Co. v. Holland L.P., 867 F.3d 1229, 1240 (Fed. Cir. 2017) (citation omitted).

In determining a patentee's entitlement to lost profits, courts often, but are not required to, apply the Panduit test,

first articulated by the Sixth Circuit. Panduit Corp. v. Stahlin Bros. Fibre Works, Inc., 575 F.2d 1152 (6th Cir. 1978). See Mentor Graphics, 851 F.3d at 1284. Under the Panduit test, "a patent owner must prove: (1) demand for the patented product, (2) absence of acceptable noninfringing substitutes, (3) his manufacturing and marketing capability to exploit the demand, and (4) the amount of the profit he would have made." Panduit, 575 F.2d at 1156. The Federal Circuit has "affirmed lost profits awards based on a wide variety of reconstruction theories in which the patentee has presented reliable economic evidence of but for causation." Georgetown Rail Equip. Co., 867 F.3d at 1243 (citation omitted).

Standards for Preclusion of Late-Produced Discovery

> Rule 26(a) requires, in relevant part, that a party
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> must, without awaiting a discovery request, provide to the other parties . . . a computation of each category of damages claimed by the disclosing party -- who must also make available for inspection and copying as under Rule 34 the documents or other evidentiary material, unless privileged or protected from disclosure, on which each computation is based, including materials bearing on the nature and extent of injuries suffered.

Fed. R. Civ. P. 26 (a)(1)(A). This rule has been interpreted as requiring that "[a] party claiming damages or other monetary relief must, in addition to disclosing the calculation of such damages, make available the supporting documents for inspection and copying as if a request for such material had been made

under Rule 34." Design Strategy, Inc. v. Davis, 469 F.3d 284, 296 (2d Cir. 2006) (citation omitted).

Rule 26(e)(1)(A) requires that

> A party who has made a disclosure under Rule 26(a) -- or who has responded to an interrogatory, request for production, or request for admission -- must supplement or correct its disclosure or response: (A) in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing; or (B) as ordered by the court.

Fed. R. Civ. P. Rule 26(e)(1)(A) (emphasis supplied).

Under Fed. R. Civ. P., Rule 37, courts may impose "a wide range of sanctions for . . . discovery abuses." Mali v. Fed. Ins. Co., 720 F.3d 387, 392 (2d Cir. 2013). Rule 37(c) addresses sanctions for a party's failure to make required disclosures. This rule provides, in relevant part:

> If a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless. In addition to or instead of this sanction, the court, on motion and after giving an opportunity to be heard:
>
> (A) may order payment of the reasonable expenses, including attorney's fees, caused by the failure;
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> (B) may inform the jury of the party's failure; and
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> (C) may impose other appropriate sanctions, including any of the orders listed in Rule 37(b)(2)(A)(i)-(vi).

Fed. R. Civ. P. 37(c) (emphasis supplied).

Rule 37(b)(2)(A) governs sanctions for a party's failure to obey discovery orders. That rule provides:

> If a party . . . fails to obey an order to provide or permit discovery, including an order under Rule 26(f), 35, or 37(a), the court where the action is pending may issue further just orders. They may include the following:
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> (i) directing that the matters embraced in the order or other designated facts be taken as established for purposes of the action, as the prevailing party claims;
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> (ii) prohibiting the disobedient party from supporting or opposing designated claims or defenses, or from introducing designated matters in evidence;
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> (iii) striking pleadings in whole or in part;
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> (iv) staying further proceedings until the order is obeyed;
>
> (v) dismissing the action or proceeding in whole or in part;
>
> (vi) rendering a default judgment against the disobedient party; . . .

Fed. R. Civ. P. 37(b)(2)(A) (emphasis supplied).

To determine whether preclusion of discovery is appropriate under Rule 37, a court must consider the following four factors: "(1) the party's explanation for the failure to comply with the disclosure requirement; (2) the importance of the [evidence]; (3) the prejudice suffered by the opposing party as a result of having to prepare to meet the new [evidence]; and (4) the possibility of a continuance." Design Strategy, 469 F.3d at 296 (citation omitted). In Design Strategy, the Second Circuit found that prejudice to the opposing party was "severe" where evidence of lost profits was not disclosed because "discovery

would have had to be reopened to determine whether [the plaintiff's] calculations were proper." Id. at 297.

Pharma Spreadsheet

Novartis does not seek reconsideration of the Court's ruling precluding its use of the Agreements at trial.[2] Novartis contends only that it should not be precluded from relying on the Pharma Spreadsheet at trial. Novartis presents substantially the same arguments as to why the Pharma Spreadsheet should not be precluded that it presented at the April 24 hearing. These arguments are unavailing and the Court declines to reconsider its April 24 ruling precluding the use of the Pharma Spreadsheet in this litigation.

a. Explanation for failure to produce

Novartis does not offer a satisfactory explanation for its failure to timely produce the Pharma Spreadsheet. While, as explained at the April 24 conference, there is no indication that this spreadsheet was withheld in bad faith, Novartis's failure to timely produce this important set of calculations reflects an absence of adequate care and diligence in Novartis's prosecution of its damages claims. Novartis was required by Rule 26(a) to disclose its computation of damages and, upon

[2] Novartis contends the Agreements are only relevant to rebut Regeneron's contention, which Novartis considers dubious, that Pharma does not sell Lucentis.

request, the records upon which it relied for that computation, and by Rule 26(e) to timely supplement this disclosure if Novartis discovered it was incorrect or incomplete. The Pharma Spreadsheet -- apparently the only document produced to date that calculates Pharma's lost profits -- plainly falls within this requirement.

Novartis contends that the schedule in this case, which did not require responses to contention interrogatories to be served until April 5, 2019, the same day the parties exchanged opening expert reports, allowed it to wait until that day to disclose that it would only seek Pharma's lost profits here, and not the lost profits experienced by both Pharma and its distributors. Not so. Rule 26(a) required it to explain its computation for damages in its initial disclosures, Rule 26(e) required it to promptly supplement its computation, and Regeneron's requests also required it to be produced. Indeed, Novartis produced other financial data during the discovery period that it believed was relevant to discovery of its damages theory.

To explain its failure to produce the Pharma Spreadsheet before the close of discovery, Novartis characterizes the Pharma Spreadsheet as a correction of a previously produced spreadsheet that combined Pharma's profits with its third-party affiliates' profits. Novartis argues that the initial combination of affiliate and Pharma financial information had been inadvertent.

At the April 24 Conference, Novartis explained that it was only in preparing its expert report on damages, which was due on April 5, that it realized it needed to separate out Pharma's profits alone. This explanation for the delay does not alter the conclusion that the delay reflects a lack of due diligence on the part of Novartis.

b. Importance

The Pharma Spreadsheet is important in the calculation of Novartis's lost profits, which is why Novartis produced it at the time it served the expert report from its damages expert. But, according to Novartis, its preclusion will not prevent it from proving its lost profits.

Novartis's theory of lost-profits damages hinges on the profits that Pharma would have made from its sale of Lucentis to its affiliates -- which in turn sell Lucentis on the open market -- but for the sale of the accused product. According to Novartis, the Pharma Spreadsheet streamlines the calculation of lost profits, but is not essential to its ability to calculate lost profits. Novartis asserts that its expert can rely on assumptions about what share of the sales or profits -- as reflected in a timely-produced spreadsheet -- were attributable to Pharma as opposed to its distributor affiliates. It remains to be seen whether an expert report calculating lost profits on the basis of assumptions -- rather than on records showing the

actual profits made by Pharma alone -- would be sufficiently reliable to allow the calculation to be admissible at trial, or if admissible, persuasive. In any event, Novartis asserts that the late-produced Pharma Spreadsheet is useful but not critical to proof of its lost profits.

c. Prejudice

According to Regeneron, the principal prejudice it has suffered is the ability to explore during the discovery period the nature of the closed market between Novartis and its affiliates. In particular, it claims to have lost the ability to test during that period the extent to which the inter-company transfers reflect fair market value or other factors like taxation and the impact of country-specific factors on the transfers.

Regeneron has not shown it would have succeeded, over Novartis's objection, in pursuing the extensive discovery of the inter-company relationships and the country-specific conditions it outlines in opposition to this motion. Regeneron has not shown that, whatever those relationships and conditions are, they would have been any different because of the entry of Eylea into the market.

Moreover, the extent of any prejudice to Regeneron is minimized by Novartis's timely production of other financial records. These include a spreadsheet showing the combined

profits of Pharma and its affiliates, and other documents showing country-by-country unit sales, net sales and gross sales. Regeneron has deposed a Novartis 30(b)(6) witness regarding various financial matters. It also declined Novartis's offer of a follow-up 30(b)(6) deposition to answer questions about the Pharma Spreadsheet. Thus, while Regeneron has shown that it has suffered some prejudice by receiving an altered calculation of damages only after the close of discovery, it has not shown that the late production of the Pharma Spreadsheet has caused it significant prejudice.

d. Possibility of a Continuance

Neither Regeneron nor Novartis seeks a continuance to further address this issue. This case was filed some seven years after similar claims for patent infringement were brought by Novartis against other companies and over three years after the expiration of the patent at issue. Expeditious resolution of this matter is in the interest of all parties.

Having again weighed the four factors to be considered before imposing sanctions under Rule 37, it is appropriate to sanction Novartis for its failure to timely produce the Pharma Spreadsheet. The Court's April 24 ruling precluding use of the Pharma Spreadsheet in this litigation remains in place.

Conclusion

Regeneron's April 16, 2019 request to preclude Novartis from offering at trial the Agreements or the Pharma Spreadsheet is reaffirmed and Novartis's May 1, 2019 request for reconsideration is denied.

Dated: New York, New York
July 12, 2019

DENISE COTE
United States District Judge